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ATTACHMENT B

510(k) Summary of Safety and Effectiveness

DEC 30 2010

Date: September 13, 2010

Submitter: National Advanced Endoscopy Devices, Inc.
22134 Sherman Way
Canoga Park, CA 91303
Telephone: 818.227.2720
Fax: 818.227.2724
Contact Person: Gayle M. Butler
Compliance Manager

Product:
Trade Name: AED Resectoscopes
Classification: Class II
Common Name: Resectoscope
Classification Name: Resectoscope
(FJL, 21 CFR 876.1500)
Resectoscope, Working Element
(FDC, 21 CFR 876.1500)
Electrode, Electrosurgical, Active, Urological
(FAS, 21 CFR 876.4300)

Predicate Devices: Resectoscope E-Line, Richard Wolf, **K980302**
Resectoscopes, Karl Storz, **K954050**

Device Description: Resectoscopes are used in transuretheral resection of the prostate (TURP) and in transuretheral resection of bladder tumors (TURB). They consist of:

- Endoscope
- Resectoscope sheaths with obturators
- Working Element
- Electrodes

The devices are reusable and provided non-sterile. They must be cleaned and sterilized before use.

The body contact materials are surgical grade stainless steel which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

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Intended Use: Resectoscopes are used for endoscopically controlled ablation of tissue. They are used for examination, diagnosis and/or therapy in conjunction with endoscopic accessories in the various medical disciplines such as Urology and Gynecology.

Comparison to Predicate Device: Design analysis and comparison confirm that basic functional characteristics are substantially equivalent to the predicate devices cited and raise no new issues of safety and effectiveness.

Performance Standards: The devices conform to ISO 8600-4:1997, 8600-1:2005, 8600-3:1997, 8600-5:2005, 8600-6:2005 and IEC 60601-2-2 2006, IEC 60601-2-18 Edition 3.0 2009-08, IEC 60601-2-2 Edition 5.0 2009-02 and IEC 60601-2-2:2009.

Conclusion: Based on the technical information provided, intended use and performance information provided in this premarket notification, **AED Resectoscopes** have been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Gayle Butler
Compliance Manager
National Advanced Endoscopy Devices, Inc.
22134 Sherman Way
CANOGA PARK CA 91303

DEC 30 2010

Re: K102663
Trade/Device Name: AED Resectoscopes consisting of working elements, standard and continuous irrigation, resectoscope sheaths, coagulation and cutting electrodes, standard timberlake (deflecting) and visual obturators and endoscopes.
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: II
Product Codes: FJL, FDC and FAS
Dated: December 21, 2010
Received: December 27, 2010

Dear Ms. Butler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT A

DEC 30 2010

INDICATIONS FOR USE

510(k) Number (if known): K 102663

Device Name: AED Resectoscopes consisting of working elements, standard and continuous irrigation, resectoscope sheaths, coagulation and cutting electrodes, standard timberlake (deflecting) and visual obturators and endoscopes.

Indications for Use: Resectoscopes are used for endoscopically controlled ablation of tissue. They are used for examination, diagnosis and/or therapy in conjunction with endoscopic accessories in the various medical disciplines such as Urology and Gynecology.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102663